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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/805,353	03/13/2001	Cayetano Gonzalez	9845-015	1937

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EXAMINER

FRIEND, TOMAS H F

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 05/13/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/805,353

Applicant(s)

GONZALEZ ET AL.

Examiner

Tomas Friend

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-133 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-133 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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Detailed Action

Status of the Application

An amendment, a raw sequence listing, and an Information Disclosure Statement (Paper Nos. 5, 6, and 7) were received on 05, 20, and 06 September 2001 respectively.

Status of the Claims

Claims 1-133 are pending in the present application and are subject to restriction and election of species requirements.

Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-9 and 122, drawn to a method of engineering one or more binding macromolecules, classified in one of class 435, and one of numerous subclasses, depending on the target, method of screening, and macromolecule.
- II. Claims 10-44 and 123-127, drawn to a method of engineering one or more binding polypeptides, classified in class 435, and one of numerous subclasses depending on the target and method of screening.
- III. Claims 45-56, 128, and 129, drawn to a computer system and computer-readable medium, classified in class 700, subclass 90.
- IV. Claims 57-65 and 130, drawn to a polypeptide and associated vector and cell, classified in class 530, subclass and one of numerous subclasses, depending on the polypeptide.
- V. Claims 66 and 68-70, drawn to a method for altering the function of a cellular protein, classified in class 435, subclass 455.

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- VI. Claim 67, drawn to a cell comprising a nucleic acid encoding an altered cellular protein, classified in class 435, and one of numerous subclasses, depending on the type of cell.
- VII. Claim 71, drawn to a cell comprising a cellular protein with altered function, classified in class 435, one of numerous subclasses, depending on the type of cell.
- VIII. Claims 72-76 and 131, drawn to a method for assaying for one or more target polypeptides in a sample, classified in class 436, subclass 501.
- IX. Claims 77-80, drawn to a method of determining the cellular localization of a target protein, classified in class 436, subclass 86.
- X. Claims 81-89, drawn to a method for assaying for target proteins in a sample from an organism, classified in class 435, digest 15.
- XI. Claims 90-101, drawn to a library comprising recombinant organisms, classified in class 435, digest 23.
- XII. Claims 102-113, 132, and 133, drawn to a polypeptide array, classified in class 435, digest 35.
- XIII. Claims 114-117, drawn to a polypeptide-RNA fusion array, classified in class 435, digest 36
- XIV. Claims 118-121, drawn to a method of purifying one or more selected proteins from a sample, classified in class 530, subclass 810.

Claims 1-9 link inventions I and II. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 1-9. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable.

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In re Ziegler, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because:

Inventions II and III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the method of Invention II can be practiced without the use of the apparatus of Invention III.

Inventions V and Inventions VI and VII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the method of Invention V can be used to produce Inventions VI or VII.

Inventions I and II and Inventions IV, VIII, and XI-XIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case both of the methods of Inventions I and II can be used to produce any of Inventions IV, VIII, and XI-XIII.

Inventions III and Inventions IV, XII, and XIII are related as apparatus and product made. The inventions in this relationship are distinct if either or both of the following can be shown: (1) that the apparatus as claimed is not an obvious apparatus for making the product and the apparatus can be used for making a different product or (2) that the product as claimed can be made by another and materially different apparatus (MPEP § 806.05(g)). In this case the apparatus of Invention III can be used to engineer all three of Inventions IV, XII, and XIII.

Inventions IV and XI-XIII and Inventions V, VIII-X, and XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another

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materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the individual or collected products of Inventions IV and XI-XIII can be used in any of the methods of Inventions V, VIII-X, and XIV.

Inventions I, II, V, VIII-X, and XIV are different and patentably distinct methods because they involve different method steps, starting materials, reagents, and/or reaction conditions and/or produce different products or results.

Inventions IV, VI, VII, and XI-XIII are different and patentably distinct compositions because they comprise different biological entities such as peptides, polypeptides, nucleic acids, and/or cells alone or in libraries, arrays, or collections, and/or encode or possess different biological molecules having different functions. The different compositions of matter have different methods of making and using and are classified into different classes and subclasses.

Because these inventions are distinct for the reasons given above and

- a. have acquired a separate status in the art as shown by their different classification ;
- b. have different and separately burdensome: manual and/or computer: structure, name and bibliographical searches; and
- c. have divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under CFR 1.17(h).

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Election of Species

This application contains claims directed to patentably distinct species of the claimed invention. If applicant elects Invention I, applicant is required to elect a single embodiment of the claimed invention that specifies each of the following A-C:

- A. species of binding macromolecule,
- B. ultimate species of target macromolecule, AND
- C. all method steps performed including all rational engineering methods (i) and (ii).

If applicant elects Invention II, applicant is required to elect a single embodiment of the claimed invention that specifies each of the following A-E:

- A. ultimate species of target polypeptide,
- B. species of all domains present in the precursor polypeptide (e.g. from claim 12),
- C. all method steps included in (i) and (ii),
- D. species of methods based on *a priori* chemical and physical principles or rules derived from empirical knowledge or knowledge in the art used (see claim 28), AND
- E. all method steps performed including all measuring and repeating steps.

If applicant elects Invention IV, applicant is required to elect an ultimate species of polypeptide (i.e. amino acid sequence), and what function is encoded by the fusion partner, if present.

If applicant elects Invention V, applicant is required to elect an ultimate species of first cellular protein (by name and function) AND an ultimate species (i.e. amino acid sequence) of binding protein.

If applicant elects Invention VI, applicant is required to elect an ultimate species of nucleic acid (i.e. nucleotide sequence).

If applicant elects Invention VII, applicant is required to elect an ultimate species (i.e. amino acid sequence) of cellular protein with altered function.

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If applicant elects Invention VIII, applicant is required to elect a species for each of the following A-C:

- A. ultimate species (by name(s)) of target polypeptide(s)
- B. species of binding polypeptides, AND
- C. species of assaying, including all method steps required.

If applicant elects Invention IX, applicant is required to elect a species for each of the following A-D:

- A. ultimate species (by name) of target protein,
- B. ultimate species (i.e. amino acid sequence) of binding protein,
- C. species of cell, AND
- D. species of assaying including required method steps.

If applicant elects Invention X, applicant is required to elect a species for each of the following A-D:

- A. ultimate species of target protein (by name),
- B. species of organism,
- C. species of binding polypeptides, AND
- D. species of assaying, including required method steps.

If applicant elects Invention XI, applicant is required to elect a species for each of the following A-C:

- A. species of organisms presenting the library,
- B. ultimate species of binding polypeptides required to be present in the library (i.e. their amino acid sequences), AND
- C. the number of binding polypeptides present in the library.

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If applicant elects either of Inventions XII or XIV, applicant is required to elect a species for each of the following A and B.

A. species of binding polypeptides required to be present (i.e. amino acid sequences),

AND

B. species of selected proteins expressed in the organism to which the binding polypeptides bind.

If applicant elects Invention XIII, applicant is required to elect a species for each of the following A and B.

A. species of binding polypeptide-RNA fusions required to be present (i.e. amino acid and nucleotide sequences),

AND

B. species of selected proteins.

The species are distinct, each from the other, because they have different chemical or biological structures with different chemical, physical, and/or pharmacological properties. Alternatively or additionally, the method steps involved require different reagents and reaction conditions, produce different results, and require different starting materials. Therefore, different issues of enablement and patentability apply to each species and each species represents patentably distinct subject matter.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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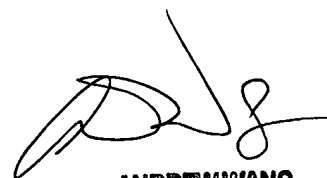
Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Tomas Friend**, telephone number **(703) 308-4548**. The examiner's schedule is an increased flex-time schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2742.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist at (703) 308-1235.

Tomas Friend, Ph.D.
05 May 2003



ANDREW WANG
SUPERVISORY PATENT EXAMINER
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